REMARKS/ARGUMENTS

This is in full and timely response to the Office Action mailed February 21, 2003.

By this Amendment, claim 1 was amended to recite that the reaction solution is a PCR reaction solution. Support for this amendment can be found variously throughout the specification, for example, at page 19, lines 7-8. Claim 7 was placed in independent form. Claim 12 was amended to add the step of storing the homogenized sample in homogenized state until amplification of a nucleic acid. Support for this amendment can be found variously throughout the specification, for example, at page 8, line 24 to page 9, line 8. The Specification was amended at page 11 as recommended by the examiner to be consistent with the previous amendment to the sequence on page 12. No new matter was added. Claims 1 – 12 are pending in this application, with claims 1, 7 and 12 being independent. By this Amendment, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Applicant thanks the examiner for indicating that claims 7-10 contain allowable subject matter. Accordingly, claim 7 was placed in independent form, and accordingly, claims 7-10 are in allowable condition.

Objections to the Specification

The Office Action objects to the specification for failing to comply with the Sequence Rules regarding page 12. A telephone conference with the examiner indicated that Applicants' previous Amendment to page 12 overcomes this objection. During the telephone discussion, the examiner suggested that the specification also be amended at the bottom of page 11 to remove the terms "GH20" and "GH21" from the immediate introduction to the sequence listing. Applicant thanks the examiner for his suggestions, and has amended the specification accordingly. Withdrawal of this objection is respectfully requested.

Rejections under 35 U.S.C. §112

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Applicant respectfully traverses this rejection.

The examiner alleges that the phrase in claim 1 "directly adding the homogenized sample to a reaction solution to amplify the nucleic acid," is indefinite alleging that it is unclear "to what solution the sample is being added to." While not acknowledging the propriety of the rejection, the applicant has amended claim 1 to recite that the reaction solution is a PCR reaction solution, mooting this rejection. Withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §102

Claims 1-6 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by Steiner et al., 23 Nucleic Acids Research 2569 (1995) ("Steiner"). Applicant respectfully traverses this rejection.

Claim 1 recites a method for synthesis of nucleic acids to amplify an intended nucleic acid from a sample which comprises: homogenizing a living body-derived sample to produce a homogenized sample consisting essentially of said living body-derived sample and a surfactant; and then directly adding the homogenized sample to a PCR reaction solution to amplify the nucleic acid.

Steiner discloses that a plant tissue can be ground into dry material, and a rapid one-step extraction (ROSE) buffer containing 1% sodium lauryl sarkosyl can be added to the ground lyophilized tissue (page 2569, column 1). Also, Steiner discloses that 400 µl of ROSE containing 1% sodium lauryl sarkosyl is added to a 100 µl human blood sample (page 2570, col. 1-2), and polyvinylpolypyrrolidone (PVPP)is added to the ground lyophilized tissue. That is, Steiner's combination of the tissue and the ROSE buffer contains PVPP. Although ROSE contains a surfactant, it is clear that ROSE also includes additional compounds such as 1% polyvinylpolypyrrolidone (PVPP) which must settle from the tissue sample after DNA is extracted from the tissue using ROSE. That is, Steiner discloses that "The samples are placed ... to allow the tissue and PVPP to settle before aliquots of extract are taken for ... amplification by PCR (page 2569, col. 1). Thus, Steiner's PVPP is allowed to settle to make the sample no longer homogenized before amplification.

Steiner fails to teach or suggest each and every feature of claim 1 because: 1) the tissue/ROSE combination of Steiner does not consist essentially of the living body sample (tissue) and a surfactant - it also includes other compounds such as PVPP which materially affect the claimed homogenizing step; and, 2) since such compounds as PVPP tend to settle, it is clear that the tissue/ROSE combination of Steiner is not homogenized. Note that the term, "homogenized" in the present specification is defined (page 6, last two lines) as a state where "nucleic acids are uniformly dispersed in a sample liquid."

A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Steiner fails to disclose, either explicitly or implicitly, teach or suggest at least the above-noted features recited in independent claims 1-6 and 11, Steiner cannot anticipate the claims. At least in view of the foregoing, claims 1-6 and 11 are allowable, and the rejection should be reconsidered and withdrawn.

Claim 12 is rejected under 35 U.S.C. 102(b) as anticipated by Liu et al., "Effects of three Sample Preservation Method on Total DNA Preparation of Porcine Whole Blood," 21 Di-San Junyi Daxue Xuebao 25 (1999) ("Liu"). Applicant respectfully traverses this rejection.

Claim 12 recites a method of sample storage, which comprises: homogenizing a living body-derived sample to produce a homogenized sample consisting essentially of said living body-derived sample and a surfactant; and then storing the homogenized sample in homogenized state until amplification of a nucleic acid.

As discussed in the specification, the anionic surfactant is added to the sample to be amplified, and apart from this, a nonionic surfactant is added to the amplifying reaction solution. While the anionic surfactant is used for storage, the nonionic surfactant is used only for amplification. It is not desirable that both the anionic surfactant and the nonionic surfactant are added to the sample for storage.

Liu discloses that blood samples can be stored following the addition of SDS-EDTA to the blood samples. However, Liu makes no mention of the use of any type of surfactant in its storage method. The Office Action argues that SDS-EDTA can be considered a surfactant.

However, Liu does not disclose, teach or suggest that the anionic surfactant is used for storage, the nonionic surfactant is used only for amplification, or that it is not desirable that both the anionic surfactant and the nonionic surfactant are added to the sample for storage.

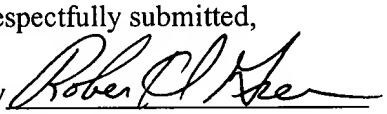
A document can only anticipate a claim if the document discloses, explicitly or implicitly, each and every feature recited in the claim. Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Since Liu fails to disclose, either explicitly or implicitly, teach or suggest at least the above-noted features recited in independent claims 12, Liu cannot anticipate the claim. At least in view of the foregoing, claim 12 is allowable, and the rejection should be reconsidered and withdrawn.

Conclusion

For the foregoing reasons, claims 1-12 are allowable, and the present application is in condition for allowance. Accordingly, favorable reexamination and reconsideration of the application in light of these amendments and remarks is courteously solicited. If the examiner has any comments or suggestions that would place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number below.

Dated: May 21, 2003

Respectfully submitted,

By 

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 180013 for any such fees; and applicant(s) hereby petition for any needed extension of time.